

TCT-531

Use of SpiderFX™ Embolic Protection Device vs. Distal Embolic Event: Hospital Length of Stay, Operating Room Time, Costs and MortalityEric J. Dippel¹, Niraj Parikh², Katrina L. Wallace²¹Midwest Cardiovascular Research Foundation, Davenport, IA, ²Covidien, Mansfield, MA

Background: Distal embolization (DE) is a potential complication of percutaneous atherectomy and other endovascular procedures that can lead to poor outcomes for the patient and escalated costs for hospitals. Embolic protection (EP) devices have been shown in several studies to have a low failure rate, and thus reduce the incidence of these events. This study compared inpatient hospital costs and resource utilization in two non-coronary (presumed lower extremity) atherectomy patient populations: (1) a DE event group, and (2) a SpiderFX™ Embolic Protection Device (Covidien, Plymouth, MN) group.

Methods: All inpatient discharges for atherectomy of non-coronary vessels (ICD-9-CM procedure code 39.50) were selected from a comprehensive hospital admissions database (Premier Perspective CY2006-Q3 of CY2012). Of these, DE patients were identified using ICD-9-CM diagnosis codes (444.xx, 434.0, and 434.1). Patients using a SpiderFX™ Device were identified using a product keyword search. Discharges in both the groups were matched 1:1 using propensity score methodology, adjusting for age, gender, race, region and severity. Hospital length of stay, operating room (OR) time, costs and inpatient mortality were compared between the groups.

Results: A total of 624 matched pairs were identified for the final analysis. Hospital stay averaged 1.4 days longer in the DE patients ($p<0.0001$) compared to the SpiderFX™ Device patients. OR time was 38 minutes longer for DE patients ($p=0.02$). Total costs were higher but not statistically significant for the DE group (\$21,709 vs. \$19,948, $p=0.10$). Room and board, pharmacy, laboratory and diagnostic costs were all significantly higher for DE than for the SpiderFX™ Device ($p<0.05$). The inpatient mortality rate was higher in the DE group but not statistically significant (1.8% vs. 0.80%, $p=0.13$).

Conclusions: The use of the SpiderFX™ Device is strongly associated with shorter hospital stays and shorter OR times. Cumulatively, these findings demonstrate embolic protection devices such as the SpiderFX™ Device may significantly reduce consumption of hospital resources.

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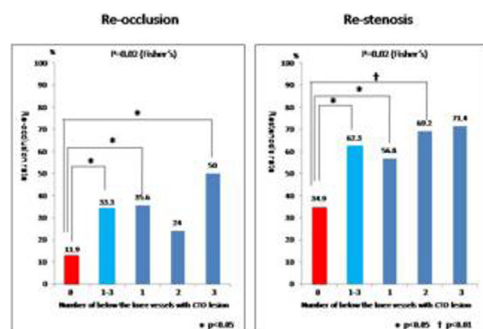
Impact of below the knee lesions to outcome in patients implanted stent for superficial femoral artery chronic total occlusion lesion.Maoto Habara¹, Yoshihisa Kinoshita¹, Tetsuo Matsubara², Kenya Nasu², Takahiko Suzuki¹, Mitsuyasu Terashima¹¹Toyohashi Heart Center, Toyohashi, Japan, ²Toyohashi Heart Center, Toyohashi, Aichi

Background: The purpose of this study was to identify the relationship between below the knee (BTK) lesions and outcomes after endovascular treatment (EVT) of chronic total occlusion (CTO) lesion in the superficial femoral artery (SFA).

Methods: From June 2001 to November 2011, 209 atherosclerosis obliterans patients underwent endovascular therapy for only SFA CTO lesions with self-expanding stents. After the EVT, final angiography was performed to evaluate the blow the knee lesions and number of vessels (0 - 3) in BTK with CTO lesions were counted. Within them, 120 limbs in 120 patients were performed 9 months follow up angiography.

Results: In total, 31 patients (25.8%) were showed in-stent occlusion and 63 patients (52.5%) were revealed in-stent restenosis including stent occlusion. The patients with stent occlusion were more frequently observed BTK lesions at stent implantation compared to the patients without stent occlusion (83.9% vs 58.4%; $p=0.02$). Similarly, the patients with in-stent restenosis were also more frequently observed BTK lesions (76.2% vs 45.6%; $p<0.001$). The re-occlusion rate was significantly higher in the patients with 1 or 3 BTK lesions than patients without BTK CTO lesion. In addition, the restenosis rate was also higher in the patients with 1 or 2 BTK CTO lesions than patients without BTK lesions.

Conclusions: Re-occlusion and restenosis rate of the patients treated SFA CTO lesions may be associated to the distal run-off vessel disease.



TCT-533

Drug-Eluting Balloon for treatment of superficial femoral artery in-stent restenosis. Two years results from an Italian registry.Vittorio Virga¹, Eugenio Stabile², Luigi Salemmi³, Angelo Cioppa⁴, Giuseppe Giugliano⁵, Tullio Tesorio⁶, Linda Cota⁷, Grigore Popusoi⁸, Armando Pucciarelli⁸, Linda Brevetti⁸, Anna Sannino⁹, Vittorio Schiano⁹, Giancarlo Biamino¹⁰, Giovanni Esposito⁵, Paolo Rubino⁸¹Clinica Montevergine, Mercogliano, Avellino, Italy, ²Clinica Montevergine, Mercogliano, Italy, ³Clinica Montevergine, Mercogliano (AV), Naples, Italy, ⁴Montevergine Clinic, Avellino, Italy, ⁵University of Naples Federico II, Naples, Italy, ⁶clinica montevergine, mercogliano, Italy, ⁷clinica montevergine, mercogliano, avellino, ⁸Montevergine Clinic, mercogliano, Italy, ⁹University of Naples Federico II, Naples, Italy, ¹⁰Clinica Montevergine (Mercogliano, AV Italy), Mercogliano, Italy

Background: The patency rate of treated SFA has been improved through use of the self-expanding nitinol stents. As the population with SFA stenting continues to increase, occurrence of in-stent restenosis (ISR) has become a thoughtful problem. The use of DEB has showed promising results in reducing restenosis recurrence in coronary stents. Accordingly, the purpose of this prospective registry was to evaluate the safety and efficacy, at 2 years, of the use of drug-eluting balloons (DEB) for the treatment of superficial femoral artery (SFA) in-stent restenosis (ISR).

Methods: From December 2009 to December 2010, 39 consecutive patients underwent PTA of SFA-ISR in our institution. All patients underwent conventional SFA PTA and final post-dilation with paclitaxel-eluting balloons (IN.PACT, Medtronic, Minneapolis, Minnesota). Clinical follow-up and duplex ultrasonography scan were performed at 30 days, and at 3, 6, 12, 18 and 24 months post-procedure. Repeat angiography was performed when proximal flow velocity ratio (PVR) was between 2.4 and 5.0 (intermediate restenosis) and when the patient had clinical symptoms or > 5.0 (severe restenosis) regardless clinical symptoms and in case of stent occlusion.

Results: Technical and procedural success was achieved in every patient. No in-hospital major adverse cardiac and cerebrovascular events occurred. At 2 years, 2 patient died (1 due to heart failure and 1 due to myocardial infarction). Primary endpoint, primary patency rate at 24 months, was obtained in 70.3% (26 patients). The presence of an occlusive restenosis at the time of treatment was not associated with an increased restenosis rate, when compared with non-occlusive restenosis, at 2 years.

Conclusions: The data suggest that adjunctive use of DEB for the treatment of SFA-ISR represents a potentially safe and effective therapeutic strategy. These data should be considered hypothesis-generating to design a randomized trial.

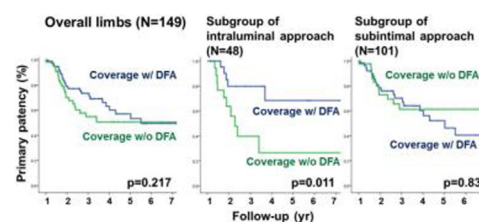
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To cover or not to cover deep femoral arteries in stenting for bifurcation lesions of superficial femoral arterySung-Jin Hong¹, Young-Guk Ko¹, Jung-Sun Kim¹, Myeong-Ki Hong¹, Yang soo Jang¹, Donghoon Choi¹¹Severance Cardiovascular Hospital, Yonsei University, Seoul, Korea, Republic of

Background: We evaluated the clinical impact of different stenting strategies, to cover or not to cover deep femoral arteries (DFA) in proximal superficial femoral artery (SFA) stenting, on the patency of SFA and to identify subgroups of patients for whom these different stenting strategies have stronger association with better patency for SFA bifurcation.

Methods: Between 2005 and 2012, 149 limbs stented at proximal SFA were retrospectively enrolled and classified into 2 groups according to stenting strategies; 85 limbs (57%) with coverage of DFA, group 1 and 64 limbs (43%) stented without coverage of DFA, group 2. The fate of DFA and primary patency of SFA were compared.

Results: Flow-limitation of DFA after stenting were observed in 14 limbs (9%) for overall, 10 limbs (12%) in group 1 and 4 limbs (6%) in group 2 ($p=0.25$). 85 limbs had follow-up CT angiography within 2 yrs and no stenosis of DFA were observed in both groups. Primary patency of SFA at 1 yr and 3 yr for overall limbs was 75% and 56%. Primary patency was not significantly different between 2 groups ($p=0.22$), although there was a trend of higher patency in group 1 up to 2 yrs. In subgroup analysis, there was a significant interaction between stenting strategy and approach method ($p=0.03$). Group 1 had significantly higher patency in subgroup of intraluminal approach ($p=0.01$), whereas there were no difference in patency between 2 groups in subgroup of subintimal approach ($p=0.84$).



Conclusions: The incidence of jailed DFA was acceptable and coverage of DFA in stenting the proximal SFA had higher primary patency, especially with intraluminal approach.

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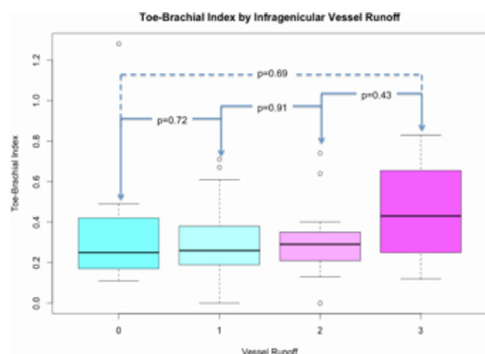
Correlation of Toe-Brachial Indices with Infragenicular Arterial Patency in Critical Limb Ischemia

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Background: Current ACC/AHA guidelines recommend toe-brachial indices (TBI) for diagnosis of peripheral arterial disease when ankle-brachial indices are unreliable due to non-compressible vessels. We sought to investigate how well TBI correlates with Rutherford classification and infragenicular arterial patency in critical limb ischemia (CLI).

Methods: Between July 2011 and February 2013, among patients who presented to the Cleveland Clinic Lower Extremity Wound Clinic with Rutherford Category 4-6 symptoms, 41 patients had TBI and lower extremity angiography performed. The correlation between TBI, Rutherford Category, and infragenicular arterial patency was evaluated.

Results: The median TBI for Rutherford Category 4, 5, and 6 symptoms was 0.32 ± 0.25 (SD), 0.24 ± 0.29 (SD), and 0.30 ± 0.20 (SD), respectively. The median TBI for 0, 1, 2, and 3-vessel runoff was 0.25 ± 0.36 (SD), 0.26 ± 0.21 (SD), 0.29 ± 0.20 (SD), and 0.43 ± 0.29 (SD), respectively. There was no statistically significant difference between TBI and Rutherford category ($p=0.42$) or number of patent runoff vessels below the knee ($p=0.80$).



Conclusions: In a small population of patients, TBI had a non-significant correlation with infragenicular runoff. TBI did not correlate with Rutherford classification. Patients with a high index of clinical suspicion for CLI should undergo further angiographic evaluation when revascularization may improve outcomes.

TCT-536

Pooled Analysis of the CONFIRM Registries: Outcomes in Elderly Patients Treated with Orbital Atherectomy for Peripheral Arterial Disease

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Background: The elderly represent a growing population of patients in the community. There is a paucity of data about the outcomes of elderly patients with peripheral arterial disease who undergo orbital atherectomy.

Methods: Our analysis of the CONFIRM I-III registries includes 2995 real-world patients (4557 lesions) with 1753 patients <75 years of age (2637 lesions) and 1753 patients ≥75 years of age (1920 lesions) treated with orbital atherectomy. The primary endpoint was the composite of dissection, perforation, slow flow, vessel closure, spasm, embolism, and thrombus formation.

Results: Patients ≥75 years of age had a high proportion of females (47.5% vs. 35.3%, $p<0.001$), more patients with critical limb ischemia, longer mean lesion length (75.0 ± 74.1 vs. 69.9 ± 68.9 mm, $p=0.01$), and more treatment location below the knee (38.4% vs. 34.1%, $p<0.001$). Patients <75 years of age and ≥75 years of age had similar rates of the primary endpoint (22.0% vs. 21.3%, $p=0.81$), dissection (11.4% vs. 10.5%, $p=0.72$), vessel closure (1.7% vs. 1.1%, $p=0.13$), spasm (6.3% vs. 6.4%, $p=0.96$), and embolism (2.5% vs. 1.6%, $p=0.31$). Patients ≥75 years of age had less incidence of thrombus formation (0.9% vs. 1.6%, $p=0.03$) but higher perforation rate (1.2% vs. 0.4%, $p=0.007$) and a trend towards a higher rate of slow flow (5.3% vs. 4.0%, $p=0.08$).

Conclusions: Plaque modification with orbital atherectomy provided similar clinical outcomes in the patients <75 years of age and ≥75 years of age despite the elderly having unfavorable baseline clinical and lesion characteristics including more patients with critical limb ischemia, longer lesions, and treatment below the knee. The higher rates of perforation and trend towards increased slow flow may be explained by more extensive disease and smaller vessels.

TCT-537

Long-term Outcomes of Self-Expanding Nitinol Stent Implantation for Chronic Total Occlusion of the Superficial Femoral and Proximal Popliteal Artery

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Background: Although recent guideline show expanded indication of endovascular therapy (EVT) for superficial femoral and proximal popliteal artery (SFPA) lesion, only secondary patency rate after self-expanding nitinol stent implantation is comparable for vein-graft bypass. Long-term outcomes are necessary for stent implantation to be considered as first-line therapy. This study investigated the long-term patency rates and predictors of restenosis after self-expanding nitinol stent implantation for chronic total occlusion (CTO) in SFPA lesions.

Methods: From January 2004 to December 2011, 2742 patients with peripheral artery disease of SFPA lesion 3471 limbs underwent EVT with a self-expanding nitinol stent at 13 institutions in Japan. Of the cohort, 1036 patients, 1169 limbs, had stents implanted for CTOs in the SFPA and were followed as long as 8 years (mean 899 ± 607 days). We retrospectively investigated baseline characteristics, patency rates, clinical outcomes and predictors of loss of primary patency.

Results: Mean age was 73 ± 9 years and 28% were female patients. Fifty-nine percent of the patients had diabetes mellitus and 27% were patients with critical limb ischemia. Occluded length was 184 ± 85 mm, 74% was TASC II type C, D lesion. Mean total stent length was 203 ± 89 mm and mean stent diameter was 6.7 ± 0.8 mm, mean final balloon diameter was 5.2 ± 0.8 mm. Fifty-two percent administered cilostazol. Incidence of stent fracture was 6%. Primary, assisted primary, secondary patency rates were 42%, 63%, 76%, respectively. Mortality rate was 14%, 2.5% went to surgical bypass, 2.7% had major amputation. In the multivariate analysis, stent fracture (OR 2.52; $p=0.0016$), female gender (OR 1.73; $p=0.0005$), use of distal puncture technique (OR 1.50; $p=0.0096$), diabetes mellitus (OR 1.43; $p=0.0148$), final balloon diameter (OR 0.23; $p=0.0075$), administration of cilostazol (OR 0.65; $p=0.0052$) and use of IVUS (OR 0.71; $p=0.0342$) were factors strongly associated with loss of primary patency.

Conclusions: Although primary patency was low, secondary patency rate was acceptable.

TCT-538

Catheter directed thrombolysis in deep venous thrombosis with or without pulmonary thromboembolism

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Background: As deep venous thrombosis (DVT) treatment with anticoagulation does not resolve the thrombus formed in the vein, we wanted to study the result of catheter directed thrombolysis (CDT) in patients with acute DVT with or without pulmonary thromboembolism (PTE).

Methods: We retrospectively analysed the data of patients who presented with acute (< 10 days) or sub-acute (< 21 days) or acute on chronic DVT with or without PTE and were given CDT through Multi-Side port Catheter Infusion Sets Dual Check Valve 5F perfusion catheter (65 or 100cm from Cook's company), in our unit in the year 2012. CDT was done with streptokinase, 250,000 U as a loading dose over 30 minutes, followed by 100,000 U/h over 24 hours. CT pulmonary angio and venous colour Doppler was done before and 24 hrs after CDT was done. Success of CDT was defined as complete or partial depending on complete or reduction of thrombus burden in pulmonary arteries &/or deep veins.

Results: A total of 22 patients presented with Acute DVT in our unit [15 (68.2%) males and 7 (31.8%) females with mean age of 42.6 ± 13.6 yrs] in 2012. Out of them 11 (50%) had PTE, 6 massive and 5 sub massive and 9 had PAH. 14(63.6%) had Acute, 4 (18.2%) had sub-acute & 4 (18.2%) had acute on chronic DVT. 8 patients had predisposing factors (immobilization 4, adrenal adenoma 1, hyperhomocysteinemia 1, haemodialysis related 1, venous stenosis 1). Simultaneously IVC filter implantation in 12 (54.5%) and venous stenting in one patient was done. After 24 hrs of CDT, 11 (50%) DVT patients had complete resolution of thrombus and 11 (50%) had partial resolution (even in this group proximal thrombus in iliac veins was disappeared in all except one). Out of 11 patients who had PTE, 8 had complete resolution of thrombus and 3 had partial. Pulmonary artery pressure normalized in 7 (79- 77.8%). In 3 patients IVC filters were retrieved. One patient had puncture site hematoma which was managed conservatively. No fatal complication was noted.